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Wolverine™ Coronary Cutting Balloon®

MONORAIL®

OVER-THE-WIRE

Microsurgical Dilatation Device

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Carefully review all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

The Wolverine Over-The-Wire (OTW) Coronary Cutting Balloon Microsurgical Dilatation Device and the Wolverine Monorail (MR) Coronary Cutting Balloon Microsurgical Dilatation Device consists of a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. 2.00 mm – 3.25 mm balloon diameter models contain 3 atherotomes and 3.50 mm – 4.00 mm balloon diameter models contain 4 atherotomes. When the device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. This process, referred to as atherotomy, allows dilatation of the target lesion with less pressure.

The distal section of both devices (and the proximal section of the OTW device) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the device to and through the stenosis to be dilated. The proximal section of the MR device is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The OTW device has a dual luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The balloon with atherotomes is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the device. The device's tip is tapered to facilitate advancement of the device to and through the stenosis. All shafts have ZGlide™ (hydrophilic) coating. For MR, the ZGlide is located from the guidewire port to the distal tip of the device. For OTW, the ZGlide is located from distal of the proximal marks to the distal tip of the device.

The effective catheter length of the MR is 143 cm and the OTW is 142 cm. Marks on the proximal portion of the device shaft (for MR, one at 90 cm and one at 100 cm; for OTW, one at 90 cm and two at 100 cm) indicate the exit of the balloon device tip out of the guide catheter.

The device is provided in 6 mm, 10 mm, and 15 mm lengths. The functional atherotome length is the distance between the radiopaque marker bands. These radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the cutting balloon segment. A CLIPIT® Hypotube Clip is provided with the MR device to aid in handling the device.

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Quantity Material

One (1) Wolverine OTW Cutting Balloon Device or One (1) Wolverine MR Cutting Balloon Device

One (1) CLIPIT Hypotube Clip (MR Device Only)

INTENDED USE/INDICATIONS FOR USE

The Wolverine Cutting Balloon Device is indicated for dilatation of stenoses in coronary arteries for the purpose of improving myocardial perfusion in those circumstances where a high pressure balloon resistant lesion is encountered. In addition, the target lesion should possess the following characteristics:

- Discrete (< 15 mm in length), or tubular (10 mm to 20 mm in length)
- Reference vessel diameter (RVD) of 2.00 mm to 4.00 mm
- Readily accessible to the device
- Light to moderate tortuosity of proximal vessel segment
- Nonangulated lesion segment (< 45°)
- Smooth angiographic contour
- Absence of angiographically visible thrombus and/or calcification

CONTRAINDICATIONS

The Wolverine Cutting Balloon Device is contraindicated for use in:

- Delivery through the side cell of a previously placed stent as the deflated Cutting Balloon could become entangled in the stent.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- Exercise extreme care when treating a lesion distal to a stent. If the guidewire has passed through a stent cell rather than down the axis of the stent, the deflated device could become entangled in the stent. When treating lesions at a bifurcation, the device can be used prior to placing a stent, but should not be taken through the side cell of a stent to treat the side branch of a lesion at a bifurcation.
- The atherotomy process, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional Percutaneous Transluminal Coronary Angioplasty (PTCA). Over sizing increases the risk of perforation. To reduce the potential for vessel damage, the inflated diameter of the device should approximate a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis.
- The atherotomy process in patients who are not acceptable candidates for coronary artery bypass surgery requires careful consideration, including possible hemodynamic support during the atherotomy process, as treatment of this patient population carries special risk.
- When the device is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the device unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons (with 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure-monitoring device is recommended to prevent over pressurization.
- The atherotomy process should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- During preparation and positioning of the device, it is important that all *air and fluid* are excluded from the inflation lumen of the device until the balloon is in position at the lesion site.
- Use only the recommended balloon inflation medium (e.g. contrast medium). Never use air or any gaseous medium to inflate the balloon.
- If resistance is encountered when withdrawing the device through the guide, consider removing the guide and the device as a complete unit.

PRECAUTIONS

- Prior to performing the procedure, the device should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The device should be used only by physicians trained in the performance of PTCA.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy should be provided to the patient. Anticoagulant therapy should be continued for a period of time after the procedure as determined by the physician.
- The device is not designed for, and therefore, cannot be used to monitor in vivo arterial pressures.
- After removal from the guide catheter, system integrity should be verified prior to reinsertion.
- Use the device prior to the "Use By" date specified on the package.
- If difficulty is experienced during balloon inflation, do not continue; remove the device and do not attempt to use it. Select another device.
- Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- Prior to an angioplasty, the device should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Infusion of any medium other than a flush of heparinized normal saline through the guidewire lumen may compromise device performance.
- Do not attempt to reposition a partially deployed balloon. Attempted repositioning of a partially deployed balloon may result in severe vessel damage.
- Do not use a guidewire having a diameter greater than 0.014 in (0.36 mm).

ADVERSE EVENTS

Observed Adverse Events

The Adverse Events reported in this section were those observed in two clinical investigations: the Resistant Lesion Registry (RLR), which demonstrated the ability of the Cutting Balloon® Device to dilate lesions in a series of patients whose lesions could not be dilated with conventional balloon angioplasty; and the Global Randomized Trial (GRT), a multi-centered, randomized trial designed to compare the Cutting Balloon Device with conventional angioplasty. Twenty-nine patients were entered into the RLR and a total of 1245 patients were randomized in the GRT; 622 to the Cutting Balloon Device arm and 623 to the PTCA arm. Seven patients (5 in the Cutting Balloon Device arm and 2 in the PTCA arm) were deregistered after randomization, but before receiving the assigned treatment. Therefore, there were 1238 evaluable patients in the GRT.

In the RLR, dissection was the only in-lab complications recorded. Dissections occurred 14 times: six times prior to Cutting Balloon Device treatment; two times after Cutting Balloon Device treatment; and six times as part of the post-Cutting Balloon Device adjunctive treatment.

One patient death from a cardiac arrest and acute pulmonary edema occurred in the RLR 24-48 hours post-procedure. This patient was treated for mid-RCA lesion with a series of four inflations with a PTCA balloon catheter, followed by a single inflation with the Cutting Balloon Device. A dissection was noted following use of the Cutting Balloon Device. Adjunctive treatment included two inflations with a second PTCA balloon catheter followed by placement of a stent.

The major adverse events occurring in the GRT are listed in Table 1.

There were eight deaths among the patients randomized to the Cutting Balloon Device arm. Two deaths occurring during the procedure involved perforations. In the first case, the perforation was associated with contrast extravasation and a Grade F dissection which was treated with balloon angioplasty and one stent. Quantitative Coronary Angiography (QCA) reported Thrombolysis in Myocardial Infarction (TIMI) 3 flow with a 35% residual stenosis and persistent contrast extravasation at the end of the procedure. Tamponade developed and the patient died during surgery. An intramyocardial hematoma was identified. In the second case, the coronary artery ruptured at the Cutting Balloon Device site and the patient developed ventricular fibrillation. The patient was resuscitated and treated emergently for tamponade, but expired following Coronary Artery Bypass Graft (CABG). In both of these cases, the Cutting Balloon Device was oversized. The balloon: artery ratio, as determined by QCA, was 1.25:1 and 1.8:1, respectively.

A perforation also occurred in the death of another patient who was randomized to the Cutting Balloon Device arm, but treated with a PTCA balloon because of a failure to cross the lesion with the Cutting Balloon Device. This patient died 105 days post-procedure due to complications of a CABG performed at that time. One patient died within an hour of the procedure from a presumed re-occlusion.

A fifth patient died at 130 days post-procedure from a reported heart attack. Two deaths occurred following exacerbation of a pre-existing chronic obstructive pulmonary disease and respiratory failure (20 days), and emergency surgery for an abdominal aortic aneurysm (50 days). The remaining death was reported as the result of respiratory failure caused by chronic obstructive pulmonary disease.

Perforation was observed in five cases, all in the Cutting Balloon Device arm. As described above, in two of these cases the patient died acutely. Perforations were treated with PTCA, a stent or both.

Table 1. GRT Major Adverse Events Occurring Within 270 Days (1,238 Patients)

Adverse Event	Cutting Balloon Device*	Conventional Balloon	Difference [95% Ci]
MACE‡	13.6% (84/617)	15.1% (94/621)	-1.5% [-5.4%, 2.4%]
Death	1.3% (8/617)	0.3% (2/621)	1.0% [0.0%, 2.0%]
MI	4.7% (29/617)	2.95% (18/621)	1.8% [-0.3%, 3.9%]
Q Wave MI	1.5% (9/617)	1.1% (7/621)	0.3% [-0.9%, 1.6%]
Non-Q Wave MI	3.2% (20/617)	1.8% (11/621)	1.5% [-0.3%, 3.2%]
Emergent CABG	1.0% (6/617)	1.0% (6/621)	0.0% [-2.3%, 1.7%]
TLR§	11.7% (72/617)	14.8% (92/621)	-3.1% [-6.9%, 0.6%]
CABG (per pt.)	1.5% (9/617)	2.1% (13/621)	-0.6% [-2.1%, 0.8%]
PTCA (per pt.)	10.5% (65/617)	12.7% (79/621)	-2.2% [-5.8%, 1.4%]
Subacute Closure	1.3% (8/617)	1.6% (10/621)	-0.3% [-1.5%, 3.0%]
Bleeding Complications	0.3% (2/617)	0.0% (0/621)	0.3% [-1.9%, 0.7%]
Vascular Complications¶	0.3% (2/617)	0.2% (1/621)	0.1% [-1.9%, 1.0%]
Clinical Perforation	0.8% (5/617)	0.0% (0/621)	0.8% [-0.4%, 2.3%]

*Numbers are % (count/sample size).
†Difference = S_{CB}-S_{PTCA} SE_{Diff} = sqrt [SE_{CB}^2+SE_{PTCA}^2] CI = Diff ± 1.96*SE_{Diff}
‡Major Adverse Cardiac Events (MACE); Death, Q Wave MI, emergent CABG, target lesion CABG or TL-PTCA.
§Target lesion revascularization (TLR) at 9 months: any "clinical driven" PTCA (TL-PTCA) or bypass surgery (TL-CABG) performed on the target lesion after documentation of recurrent angina and/or evidence of myocardial ischemia by stress testing.
¶Vascular complications: Any vascular complication requiring surgical repair.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following:

- Abrupt closure
- Acute myocardial infarction
- Angina of unstable angina
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Cardiac tamponade/pericardial effusion
- Cardiogenic shock
- Cerebrovascular accident/stroke
- Coronary aneurysm
- Coronary artery bypass graft surgery
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture, or injury, possibly requiring surgical repair or intervention
- Death
- Drug reactions, including allergic reaction to contrast medium
- Embolism
- Hemodynamic compromise
- Hemorrhage or hematoma
- Hypo/hypertension
- Infection
- Minor vessel trauma
- Myocardial ischemia
- Percutaneous re-intervention
- Pseudoaneurysm (at vascular access site)
- Pyrogenic reaction
- Renal failure
- Respiratory insufficiency
- Restenosis of the dilated vessel
- Side branch occlusion
- Slow flow/no reflow
- Thrombosis
- Total occlusion of the coronary artery or bypass graft
- Transient ischemic attack
- Vasovagal reaction
- Ventricular irritability/dysfunction
- Vessel trauma requiring surgical repair or intervention
- Volume overload

Observed Device Malfunctions

There were no Cutting Balloon Device malfunctions in the RLR.

A total of 15 Cutting Balloon Device malfunctions were recorded in the GRT. Two devices failed to inflate. Thirteen cases of balloon leak or rupture were reported: 9 with the first inflation and 4 with the second inflation.

CLINICAL STUDIES

Resistant Lesion Registry (RLR)

The Resistant Lesion Registry (RLR) contains registry data on 30 lesions in 29 patients. All patients were enrolled at a single site between November 1996 and November 1999.

Study Endpoints

The primary endpoint was acute lesion success defined as a reduction in lumen narrowing of at least 20%. The secondary endpoint was procedural success.

Procedural success was defined as lesion success, a final residual stenosis of ≤ 50 after all devices are used and no major adverse events (MACE, defined as death, CABG, or non-fatal MI).

Study Population

The RLR patients were selected for treatment on the basis of failed conventional angioplasty, defined as failure to reduce the lumen diameter narrowing by > 20% and the final residual stenosis > 50% with PTCA balloon inflation pressures

> 10 atmospheres. The demographics, risk factors and prior history of these patients are shown in Table 2.

Table 2. Demographics, Risk Factors and Prior Procedures

Demographics:	
% Male	69% (20/29)
Age	65 ± 8.4
Angina Class $_{(CCS)}$	2.8 ± 0.8
Risk Factors:	
Diabetes	14% (4/28)
Smoking	39% (11/28)
HB Pressure	29% (8/28)
Hyperlipidemia	48% (13/27)
Risk Procedures:	
MI	33% (9/27)
CABG	22% (6/27)
PTCA	22% (6/27)

Methods

Patient data were obtained prospectively on 6 patients under a formal clinical protocol and retrospectively on 23 patients. For both prospective and retrospective patient groups, conventional balloon angioplasty was used as the initial treatment in all but two cases. In these two cases the Cutting Balloon® Device was used as the first treatment for dilatation of an unprotected left main, a vessel known to be resistant to PTCA dilatation. Physician discretion was used to further decrease the residual stenosis with additional adjunctive devices following treatment with the Cutting Balloon Device.

Results

Of the 29 patients entered into the RLR, balloon resistant lesions were treated in 26 native vessels and 4 saphenous vein grafts (SVGs). Patients were treated with a sequence of devices including the Cutting Balloon Device. The Cutting Balloon Device was usually used as the second (14 cases) or third (10 cases) device in each treatment sequence. In three cases, the Cutting Balloon Device failed to cross the lesion on the initial attempt. Successful crossing was achieved with the second attempt (2 cases) following an additional crossing with a PTCA balloon. In the third case there were no further attempts to cross the lesion.

In most cases, the Cutting Balloon Device was inflated once (78%, 25/32); while the number of inflations with the PTCA catheter, prior to the Cutting Balloon Device, varied from 1 (31%, 14/45), 2 (36%, 16/45), 3 (18%, 8/45), to ≥ 4 (16%, 7/45) inflations. Inflation pressures ranged from 8-16 atmospheres for the Cutting Balloon Device and 4-25 atmospheres for the PTCA catheters. The average inflation pressure for the Cutting Balloon Device was significantly less than the average pressure used for the PTCA catheters [9.3 ± 1.8 atm (n=32) versus 15.4 ± 3.6 atm (n=45), p < 0.0001].

The principal safety and efficacy results of the RLR are shown in Table 3. The primary and secondary endpoints, used for the prospectively enrolled patients, were also applied to the patients enrolled retrospectively.

Table 3. Principal Effectiveness and Safety Results of Resistant Lesion Registry (n=29 patients, 30 lesions)

Effective Measures:	**Cutting Balloon Device %, (n/N), [95% CI]**
Acute Lesion Success	78% (18/23) [56%, 93%]
Procedural Success	74% (17/23) [52%, 90%]
% DS - Initial	73% (30) [70%, 77%]
Post PTCA	51% (17) [44%, 59%]
Post CB	36% (22) [28%, 45%]
Final	16% (30) [8%, 23%]
Safety Measures:	
MACE	3% (1/30) [1%, 10%]
Dissection, Prior to Cutting Balloon	20% (6/30) [8%, 39%]
Dissection, Cutting Balloon Device + Adjunctive Use	27% (8/30) [12%, 47%]

Global Randomized Trial (GRT)

The Global Randomized Trial (GRT) was a multi-centered, randomized trial designed to compare the Cutting Balloon Device with conventional angioplasty. Patient enrollment in the GRT occurred between June 1994 and November 1996, at 31 centers in the US, Canada, France, Belgium and the Netherlands. Of the 1245 patients enrolled, 622 were assigned to the Cutting Balloon Device arm and 623 to the PTCA arm. Seven patients (5 in the Cutting Balloon Device and 2 in the PTCA arm) were deregistered after randomization but before receiving the assigned treatment. Deregistration occurred for the following reasons: resolution of the stenosis between the prior angiogram and the index procedure (3 cases), the presence of calcification requiring atherectomy (1 case), and failing to meet the inclusion criteria (3 cases).

Study Endpoints

The primary endpoint was angiographic restenosis at 6 months. Secondary endpoints included TLR and MACE at 9 months. A clinical events committee blinded to treatment assignment adjudicated all major clinical events.

Study Population

Patients, between the ages of 25 and 75 years, with atherosclerotic coronary artery disease were eligible for enrollment in the GRT if they were suitable candidates for coronary artery bypass graft surgery and the target lesions were de novo Type A or B lesions in native arteries without total obstructions or visible thrombus, and were accessible to the Cutting Balloon Device.

Methods

Patients were prospectively randomized to treatment with either the Cutting Balloon Device or PTCA. Access to the target lesion was gained through the femoral artery approach. The reference vessel diameter (located just proximal to the target lesion) was measured by quantitative angiography.

Selection of the Cutting Balloon Device with the appropriately sized balloon diameter was based on the reference vessel diameter. If necessary, tandem dilatations were allowed for lesion lengths ≤ 20 mm. Over sizing of the balloon was not recommended in the PTCA arm.

The protocol allowed for a single inflation of the Cutting Balloon Device up to 8 atmospheres for a maximum of 90 seconds. Subsequent dilatation(s) with a PTCA balloon were allowed only if the residual stenosis was > 40%. In the PTCA arm, the inflation times and pressures were left to the discretion of the investigator.

Serial inflations with a single balloon, or subsequent inflations with increased diameter PTCA balloons were allowed to achieve a ≥20% reduction in stenosis and a ≤ 50% residual stenosis. Multiple violations of the procedural protocol were reported in the Cutting Balloon Device arm [33% (212/617) of the Cutting Balloon Device subjects were not treated per protocol].

Clinical follow-up was performed at six weeks, six months and nine months. Baseline quantitative coronary angiography (QCA) was performed pre-procedure, following device use, and after the final treatment in all patients. Follow-up quantitative coronary angiography at 6 months was required in all patients. Anti-coagulation included aspirin 325 mg/day throughout the study.

Results

The acute and six months angiographic and clinical results demonstrated that the Cutting Balloon Device was similar to PTCA with respect to Procedure Success (defined as achievement of < 50% residual diameter stenosis and freedom from in-hospital major adverse cardiac events [MACE, defined as death, Q wave MI, emergent coronary artery bypass surgery, or repeat target lesion revascularization]), 30-day incidence of MACE, and Angiographic Restenosis (defined as > 50% minimum lumen diameter stenosis at follow-up angiography). The principle safety and efficacy results are shown in Table 4.

Individualization of Treatment

Avoid use in patients whose lesions possess the following characteristics: reference coronary artery diameter of less than 2.0 mm; diffuse (> 20 mm in length); total obstruction (occlusion); heavy calcification; excessive tortuosity of proximal vessel segment; moderate to extreme angulation of target lesion segment (≥ 45°); inaccessible to the device; thrombus present.

Appropriate sizing of the Flextome® Cutting Balloon Device is extremely important. Do not exceed a balloon: artery ratio of 1.1:1.

Delivery failures are likely to be more frequent with the Flextome Cutting Balloon Device than with conventional PTCA. This occurs for two reasons. First, the Flextome Cutting Balloon Device has a larger profile than a conventional PTCA catheter of the same nominal inflated diameter. Second, the materials of construction prevent the Flextome Cutting Balloon Device from being as flexible as a conventional balloon.

If you intend to use a 15 mm device, but suspect that you may have difficulty in reaching the lesion because of tortuosity, consider using a 10 mm device with tandem inflations.

Table 4. Principal Effectiveness and Safety Results (Intent-to-Treat) All Randomized Lesions Treated (1238 Patients, 1385 Lesions)

Efficacy Measures (per lesion)	**Cutting Balloon Device® (N=689)**	**PTCA (N=696)**	**Relative Risk [95% Ci]**	**Difference [95% Ci]**
Lesion Success	95.5% (642/672)	96.5% (668/692)	0.99 [0.97, 1.01]	-1.0 % [-3.1%, 1.1%]
Device Success	77.7% (473/609)	77.8% (460/617)	1.00 [0.94, 1.06]	-0.1% [-4.8%, 4.5%]
Procedure Success	92.9% (566/609)	94.7% (584/617)	0.98 [0.95, 1.01]	-1.7% [-4.4%, 1.0%]
MLD after Device (mm) Range (min, max)	2.05 ± 0.52 (672) (0.00, 4.14)	2.13 ± 0.53 (692) (0.00, 4.07)	N/A	-0.08 [-0.14, -0.03]
% DS after Device Range (min, max)	29% ± 14% (672) (-13%, 100%)	27% ± 13% (692) (-12%, 100%)	N/A	1.6% [0.1%, 3.0%]
MLD after 6 months (mm) Range (min, max)	1.63 ± 0.62 (551) (0.00, 3.44)	1.65 ± 0.61 (559) (0.00, 3.40)	N/A	-0.02 [-0.10, 0.05]
% DS after 6 months Range (min, max)	42% ± 19% (551) (-11%, 100%)	42% ± 19% (559) (-4%, 100%)	N/A	0.1% [-2%, 2%]
Restenosis Rate at 6 months	31.4% (173/551)	30.4% (170/559)	1.03 [0.87, 1.23]	1.0% [-4.5%, 6.4%]
TLR-free at 9 months*	89.3%	86.1%	1.04 [1.00, 1.08]	3.2% [-0.3%, 6.7%]
TVR-free at 9 months†	88.5%	84.6%	1.05 [1.00, 1.09]	3.9% [0.3%, 7.5%]
TVF-free at 9 months‡	86.9%	84.8%	1.03 [0.98, 1.07]	2.2% [-1.7%, 6.1%]
Safety Measures and Other Clinical Events (per patient)	**(N=617)**	**(N=621)**	**Relative Risk [95% Ci]**	**Difference [95% Ci]**
MACE ≤ 30 days	3.7% (23/617)	2.7% (17/621)	1.36 [0.74, 2.52]	1.0% [-1.0%, 3.0%]
MACE > 30 days	10.0% (62/617)	12.9% (80/621)	0.78 [0.57, 1.06]	-2.8% [-6.4%, 0.7%]
Perforations	0.8% (5/617)	0% (0/621)	N/A	0.8% [-0.4%, 2.3%]
Vascular Complications	0.3% (2/617)	0.2% (1/621)	2.01 [0.19, 21.11]	0.2% [-0.4%, 0.7%]

Numbers are % (count/sample size) or Mean ± 1 SD. CI = Confidence interval. Survivor estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.
Relative Risk = S_{CB}/S_{PTCA} SE_{RR} = sqrt [$(SE_{CB}/S_{CB}^2) + (SE_{PTCA}/S_{PTCA})$] CI = RR*exp (1.96*$SE_{RR}$)
Difference = S_{CB}-S_{PTCA} SE_{Diff} = sqrt [SE_{CB} + SE_{PTCA}^2] CI = Diff ± 1.96*SE_{Diff}
Lesion success: Lesion success was defined as the achievement of a final residual diameter stenosis of < 50% (by QCA core laboratory) using any percutaneous method. Device success: Achievement of a final residual diameter stenosis of < 50% (by QCA core laboratory) in the absence of unplanned coronary stenting, randomized treatment failure or crossover. Procedure success: Achievement of a final residual diameter stenosis of < 50% (by QCA core laboratory) in the absence of: In-Hospital MACE or target lesion revascularization within 7 days after the index procedure.
*TLR-free: Survival free from target lesion revascularization at 9 months estimated using Kaplan-Meier methods.
†TVR-free: Survival free from target vessel lesion revascularization at 9 months estimated using Kaplan-Meier methods.
‡TVF-free: Survival free from target vessels failure (death, Q wave myocardial infarction, or target vessel revascularization) at 9 months estimated using Kaplan-Meier methods.
Major Adverse Cardiac Events (MACE): Death, Q wave MI, emergent CABG, target lesion CABG or TL-PTCA. Primary endpoint: Death, Q wave MI, emergent CABG, target lesion revascularization, or subacute closure within 30 days of the index procedure. Vascular complications: Any vascular complication requiring surgical repair.

Table 5. Wolverine™ Coronary Cutting Balloon® Microsurgical Dilatation Device Compliance

Pressure ATM (kPa)	Model Diameter (mm) x Ave. Balloon Diameter (mm)								
	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
3.0 (304)	1.90	2.14	2.38	2.62	2.88	3.11	3.28	3.55	3.80
4.0 (405)	1.95	2.18	2.43	2.69	2.94	3.17	3.35	3.62	3.89
5.0 (507)	1.98	2.22	2.48	2.73	2.99	3.22	3.41	3.69	3.96
6.0 (608) NOM	2.02	2.26	2.52	2.78	3.06	3.28	3.48	3.77	4.04
7.0 (709)	2.05	2.30	2.56	2.83	3.10	3.33	3.55	3.84	4.11
8.0 (811)	2.08	2.33	2.60	2.88	3.15	3.38	3.61	3.90	4.17
9.0 (912)	2.11	2.36	2.64	2.91	3.18	3.41	3.65	3.95	4.22
10.0 (1013)	2.13	2.39	2.67	2.95	3.22	3.45	3.70	3.99	4.26
11.0 (1115)	2.15	2.41	2.69	2.97	3.25	3.48	3.74	4.04	4.31
12.0 (1216) RBP	2.17	2.44	2.71	3.00	3.28	3.51	3.78	4.07	4.34

HOW SUPPLIED

- Non-pyrogenic
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Additional Supplies

In addition to the Wolverine OTW or Wolverine MR Cutting Balloon Microsurgical Dilatation Device, the following supplies should be prepared for use:

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- ≤ 0.014 in (0.36 mm) x 300 cm guidewire(s) (Wolverine OTW Cutting Balloon Device)
- ≤ 0.014 in (0.36 mm) x 185 cm guidewire(s) (Wolverine MR Cutting Balloon Device)
- Femoral or brachial guide catheter(s) in the appropriate size and configuration to select the coronary artery
  - Minimum I.D. of 6 FR guide catheter = 0.066 in (1.68 mm) (Wolverine OTW Cutting Balloon Device, and Wolverine MR Cutting Balloon Device with 3.50 mm–4.00 mm balloon diameters)
  - Minimum I.D. of 5 FR guide catheter = 0.056 in (1.42 mm) (Wolverine MR Cutting Balloon Device with 2.00 mm–3.25 mm balloon diameters)
- Sterile saline or heparinized sterile saline
- Radiopaque contrast medium
- Three-way stopcock or infusion manifold/apparatus
- Inflation device with manometer
- 10, 12, or 20 ml (cc) luer-lock
- Hemostasis valve
- Guidewire torque device
- Other supplies and medications per local protocols

Inspection Prior to Use

All equipment to be used for the procedure, including the Wolverine Cutting Balloon Device, should be examined carefully to verify functionality. Inspection prior to use should verify that the device and sterile packaging have not been damaged in shipment and that it is ready to be used. Do not use if sterile package is damaged. The device should be prepared and tested following the directions provided below prior to insertion in the body.

Note: Do not continue to use the device if damage occurs or sterility is compromised during use.

Wolverine Cutting Balloon Device – Preparation

Caution: This is a wet negative prep procedure. Customary balloon preparation methods do not apply. These steps must be followed exactly.

1. Sizing the device to the reference artery is extremely important for a successful dilation. Over sizing the balloon increases the risk of perforation. To reduce the potential for vessel damage, the inflated diameter of the device should approximate a ratio of 1.1:1 in relation to the average diameter of the reference coronary artery.
2. Using sterile technique, remove the device in its protective hoop from its package and place onto a sterile field. Do not remove the device from its protective hoop. Do not remove the balloon protector from the device tip.
3. Connect a three-way stopcock to the balloon port. Turn stopcock lever OFF to the balloon. Prepare an inflation device with 5 cc of contrast solution (mixture must be at least 50:50 contrast medium and sterile saline).
4. Attach the inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread causing subsequent leakage and use care when connecting the device to avoid damage (e.g., shaft kink). Purge stopcock by flushing 1-2 cc of contrast medium through the middle port.
5. Turn the stopcock lever towards the middle port or open to the balloon and immediately withdraw inflation device plunger to full negative and place the inflation device in a locked position. This will maintain a constant vacuum on the device.

   Do not allow fluid into the balloon until inflation. This will maintain the folding integrity of the balloon and protect the atherotomes. If fluid has prematurely been introduced into the balloon, do not use the device. If air has been introduced into the balloon, do not use the device.
6. When the device is ready to be inserted into the body, remove the device from its protective hoop. Use care when removing the device to avoid damage (e.g., shaft kink).
7. Using straight force (not a twisting motion), pull the balloon protector distally from the device tip. For Wolverine OTW Cutting Balloon Devices, the mandrel will slide off with the balloon protector. For Wolverine MR Cutting Balloon Devices, remove the mandrel distally after removing the balloon protector.

   Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the device and replace with another.
8. The Wolverine MR Cutting Balloon Device may be coiled once and secured using the CLIPIT® Clip provided in the device package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the device. Remove the CLIPIT Clip prior to inserting the device into the patient's body.

   Note: Care should be taken not to kink the shaft of the device upon application or removal of the CLIPIT Clip.
9. Flush the guidewire lumen of the device with heparinized saline. For Wolverine MR Cutting Balloon Device flush through the distal tip of the device. For Wolverine OTW Cutting Balloon Device flush through the guidewire port of the device hub.

   Caution: When handling device, ensure the balloon and blades are not damaged during flushing of the wire lumen. Do not use if any defects are noted. Discard the protective hoop and the balloon protector.
10. Maintain device on a sterile table until ready for use.

Wolverine Cutting Balloon Device – Positioning

1. Prepare the vascular access site according to standard practice.
2. Insert a guidewire through the hemostasis valve following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.
3. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location.
4. Confirm the device is fully deflated and under vacuum. Back load the device distal tip onto the guidewire ensuring that the guidewire exits the midsection opening in the Wolverine MR Cutting Balloon Device or the wire port of the Wolverine OTW Cutting Balloon Device manifold. When loading or exchanging the device, it is recommended to thoroughly wipe the guidewire clean for better device movement on the guidewire. Guidewire position in the distal portion of the artery must be maintained while loading the balloon onto the guidewire.

   Note: To avoid kinking, advance the device slowly, in small increments, until the proximal end of the guidewire emerges from the device.
5. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the cutting balloon device.
6. Carefully load the device onto the guidewire and advance through the hemostasis valve using fluoroscopic guidance to the tip of the guide catheter.

   Caution: Holding the balloon/blade subassembly too tightly or not opening the hemostasis valve enough may result in blade induced damage to the balloon material. If unusual resistance is felt, do not advance the device through the valve. Care should be taken not to over tighten the hemostasis valve around the device shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
7. Under fluoroscopy, while maintaining guidewire position, advance the device out of the guide catheter and into the selected coronary artery. Marks on the proximal portion of the catheter shaft indicate the exit of the balloon catheter tip out of the guide catheter, and may also be used as guidance. Advance the device and position within the lesion by centering the two radiopaque markers on either end of the lesion. The cutting edge of the atherotomes are located between the radiopaque markers. Confirm that the device is centrally located within the lesion segment before proceeding with the dilatation.

Wolverine Cutting Balloon Device – Inflation

1. Under fluoroscopy, slowly inflate the device (1 atm/5 sec) to 6 atm (nominal size). Do not inflate the device above 12 atm (rated burst pressure). Refer to Table 5 or the balloon compliance chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the device.
2. When using the device on long lesion segments (those lesions in which the targeted area of dilatation exceeds the length of the Wolverine Cutting Balloon), the distal portion of the target lesion should be treated first. Then, dilatation of the proximal lesion segment may be performed. Repeat coronary arteriography after each use to evaluate results. Perform repeat dilatation if needed.

Wolverine Cutting Balloon Device – Removal

1. Deflate the device by dialing down on the inflation/ deflation device, then pull a negative vacuum. Maintain vacuum on the device and verify full deflation under fluoroscopy.
2. Repeat coronary arteriography to confirm successful result.
3. Withdraw the device into the guiding catheter. While withdrawing the deflated device and guidewire from the guide catheter through the hemostasis valve, tighten the hemostasis valve.
4. Dispose of the entire device. *For Single Use Only.*

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the American College of Cardiology/American Heart Association.

1. Management of resistant coronary lesions by the Cutting Balloon Device: Initial experience. *Bertrand et al. Cathet Cardiovasc Diagn 1997; 41:179-184.*
2. Cutting Balloon Device angioplasty for the prevention of restenosis: results of the Cutting Balloon Device global Randomized Trial. Mauri, *et al. Am J Cardiol 2002; 90:1079-1083.*

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